Difenoconazole REGISTRATION REVIEW DRA/PID TEAM MEETING AGENDA
Tuesday, May 07, 2019 11:00 AM-12:00 PM
PYS 9100
Call in Ex. 6 Personal Privacy (PP)

Meeting Goal

Update team's understanding of the risk management goals and risk assessment needs for the chemical case. Based on this updated understanding, determine the level of effort and timeframes needed to assess the potential risks of the chemical.

Team

PRD RMIB5: Cathryn Britton (BC), Jordan Page (CRM), Jill Bloom (TL),
BEAD SIAB: Diann Sims (BC), Rafael Prieto, Stephen Jarboe,
EAB: Tim Kiely (BC), Stephen Smearman, TJ Wyatt,
BAB: Monisha Kaul (BC), Andrew Lee, Tom Harty, Tara Chandgoyal, Kelly Tindall,
EFED ERB: Sujatha Sankula (BC), Greg Orrick (RAPL), Michael Lowit, Faruque Khan, Rebecca Lazarus
HED RAB4: Bonnie Cropp-Kohlligian, Thurston Morton, Connor Williams, Brian VanDeusen, Kristin Rickard,
RD HB: Cynthia Giles-Parker (BC), Lindsay Roe (PM)

Overview of Difenoconazole Registration Review EPA-HQ-OPP-2015-0401; 128847

- Difenoconazole is a triazole type fungicide first registered in 1994.
- FRAC Code 3 (Sterol biosynthesis, demethylation inhibitor)
- 51 active Section 3 registrations as of 4/29/19
- Technical registrations from Syngenta, Albaugh, Nufarm Americas
- RD – Are there any registration actions in the pipeline at this time?

Usage Information

- 2008-2013: avg annual 140,000 lbs a.i. over 6.4 million A
- Leading Ag uses (2004-2012) (avg annual lbs a.i.) on Wheat (seed treatment) (40,000), sugar beet (20,000), potato (20,000), grapes (9,000), tomato (7,000), apples (7,000), almonds (7,000), cucumber (3,000), watermelon (2,000), onions (2,000) and others
- Ag sites include terrestrial and greenhouse
- Non-ag sites include landscape ornamentals, recreational parks, institutions, golf courses, residential properties by commercial and homeowner applicators
- Formulated as flowable concentrate, emulsion (oil) in water, emulsifiable concentrate, ready-to-use solution, and liquid soluble concentrate. applied by ground and aerial spray or as a seed treatment, broadcast spray and by chemigation, bin/truck drench or in-line dip/drench or flooder, and/or in-line aqueous or fruit coating spray application.

Ex. 5 Deliberative Process (DP)

Toxicity and Exposure Data Discussion

From Problem Formulation (2015)

- Previous eco RAs identified risk concerns primarily for aquatic invertebrates, fish, birds, and mammals on a chronic basis and on an acute basis for estuarine/marine invertebrates for

certain uses (*most recent*: USEPA, 2014a). Risk concerns for terrestrial plants were limited to listed dicot species.

- Fate data suggest residues are persistent and may accumulate over repeated applications
- DWA completed in 2014
- To reduce uncertainty in the risk assessment, EFED requests that the registrant provide annual maximum application rates per acre (maximum lb ai/A/year) on all labels in addition to the currently labeled per-crop or per-season rates that remain on some labels.

From Scoping Document (2015)

- HED assessment conducted in 2014.
- Toxicology and residue chem databases are complete; No new toxicological data are required. No revision anticipated for toxicological endpoints, points of departure, or safety factors
- Acute and chronic food plus water dietary exposure estimates were less than HED's (LOC) for all pop. Subgroups. Will dietary exposure update be needed if EDWCs for triazole degradates as a class are updated?
- No revisions to residential or occupational assessments anticipated – will spray drift and volatization risk assessments be needed?
- Cumulative: No common mechanism of toxicity found for conazoles previously, however HED is interested in reevaluating

Difenoconazole REGISTRATION REVIEW Data Tracking (EFED, Please provide updates to review status)
[HYPERLINK "https://dcoppoda6prod01.cmii.epa.gov:8500/prism/orderDetails.htm?caseId=4670"] issued 1/5/17

Guideline Number	Study Title	MRID #	Study Due Date	BEAN #/Submission Date	Review Status	Signed DER?
Ecological Studies						
860.1340	Residue Analytical Method	50449802		1/6/18 DP444982		
850.3040	Field testing for pollinators	Syngenta has not been notified that the review of the lower-tiered data resulted in requirement of this study.				
850.6100	ECM/ILV	49862302 (ECM) 49862301 (ILV) 46950128 (ECM) 46950214 (ILV) 50403701				DP128847 Acceptable

SS-1113	Residue analysis of nectar and pollen in flowering crops	Syngenta has not been notified that the review of the lower-tiered data resulted in requirement of this study.				
SS-1256	Acute oral toxicity – honeybee adult	50367601		3/25/19 DP451255		
SS-1257	Acute oral toxicity – honeybee larvae	In January 2018 EFED stated, "EFED will reconsider the waiver request for the acute oral larval study with TGAI after receipt of the chronic 22-day larval study with TGAI (MRID 50449801) and review of it along with the acute 8-day larval study with a formulation (MRID 50212904). EFED will be taking into account the collective results of those two studies when reconsidering the waiver determination for the larval acute single dose study with TGAI.				
SS-1319	Semi-field testing for pollinators (tunnel or colony feeding studies)	Syngenta has not been notified that the review of the lower-tiered data resulted in requirement of this study.				
SS-1344	Chronic oral toxicity – honeybee larvae	50449801		1/6/18 DP444982		
SS-1346	Chronic oral toxicity – honeybee adult	50727701		3/25/19 DP451255		

- All DERs must be completed and signed no later than signing or risk assessment

Ex. 5 Deliberative Process (DP)

PID/DRA Proposed Schedule for discussion:

- BEAD PLUS report to Team – by Sept 2019 (**should differentiate seed treatment vs foliar**)
- Team meeting to discuss PLUS report, any label ambiguities, and coordination in modeling – Nov. 2019

- Draft HED and EFED DRAs to PRD – 4/5/20
- Final HED and EFED DRAs to PRD – 4/5/20
- PID Publication – Q3 FY21